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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,881	11/27/2000	Michel L.P.M. Verhoeven	P-4566	4027

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MEDTRONIC, INC.  
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EXAMINER

JACKSON, SUZETTE JAMIE

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/721,881

Applicant(s)

VERHOEVEN, MICHEL L.P.M.

Examiner

Jackson J Suzette

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. Applicant's amendment dated 4/15/03 has been received in application serial number 09/721,881. Claims 3, 8-11, 13-15 have been canceled.

#### *Specification*

2. The disclosure is objected to because of the following informalities: Applicant leave out information on page 6, lines 11 “( )” and (100 × /T). Appropriate correction is required.

#### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2, and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitourne et al. 6,10,483 which discloses the invention as claimed comprising: A radially expandable stent comprising a wire having a substantially uniform hydrogel coating layer thereon; wherein the layer has an average dry coating thickness of about 0.01 micrometers to about 25 micrometers; and wherein the layer has a biologically active agent, a biocompatible, hydrophilic surface. See col. 1, lines 45-47; col 2, lines 6-9, 25-31, 34-35, 40, 53-67; col. 6, lines 28-58; col 7, lines 15-17 and col. 8, lines 19-21 however Whitourne et al. does not specify that

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*the thickness of the coating has a standard deviation of no greater than 10 percent.* It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the coating thickness no greater than 10 percent standard deviation because Whitourne et al. discloses that the coatings of the invention may be thin on the order of 1-100 microns and preferably less than about 50 microns (see col. 7, lines 15-17) and that the coating is a continuous thin layer (see col. 4, line 18) of a hydrophilic polymer and/or bioactive agent that the deviation would be less than 10 percent and since they are smooth and continuous the deviation is infinitesimal.

#### ***Response to Arguments***

5. Applicant's arguments with respect to claims 1-2, and 4-8 have been considered but are moot in view of the new ground(s) of rejection. It has been noted that the previous office action objected to claim 3, but after further review the claim has been rejected. It is the examiner's opinion that a thickness of a coating with a standard deviation of not greater than about 10 percent is obvious in the art of coating for medical devices and Whitbourne et al. teaches a thinly applied coating of less than 50 microns which will not peel, or flake within an aqueous solution (col. 7, lines 15-19). If there were deviations to the coating then it would produce a rough and uneven stent which would lead to damage of the blood vessel wall along with shearing and flaking of the coating and the Whitbourne et al. patent's goal is to produce a stabilizing polymer with an active agent entrapped in an hydrophilic polymer to prevent poor adherence, too much friction, and other problems associated with hydrogel coatings.

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***Conclusion***


5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Dufresne et al. 6,537,459 ; Ragheb et al. 6,299,604 ; Lazarov et al. 6,110,204 all show related material.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

7. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3580.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

  
Suzette J. Jackson  
31 July 2003

  
David H. Willse  
Primary Examiner